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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/501,670

01/18/2005

Hideji Tajima

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27683 7590 10/30/2007  
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EXAMINER

POPA, ILEANA

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

10/30/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/501,670	Applicant(s) TAJIMA, HIDEJI	
	Examiner Ileana Popa	Art Unit 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☒ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of the invention of Group I, drawn to a carrier housing/processing apparatus, and of the species of particle in the reply filed on 08/01/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

However, since a search for the invention of Group I rendered results relevant of the invention of Group II and all species of carriers, the restriction requirement and species election requirement is hereby withdrawn. However, since a search in the patent and non-patent literature for the elected species of particle did not render results relevant for the other species, the species election requirement is maintained.

Claims 1-18 are pending and under examination.

### ***Priority***

2. It is acknowledged that a certified foreign priority paper has been received. However, an English translation has not been provided. Correction is required.

Should Applicants provide a certified translation of their foreign priority document to overcome the prior art rejection, Applicants should indicate whether the priority application is identical to the instant application, or if the priority application contains additional disclosure. If there is additional disclosure, a brief summary should be provided. Applicants should also indicate where support for each of the claim limitations

(for the independent claims) can be found in the translated priority document by page and line number. If support is not found *in ipsius verbis*, clarification on the record may be helpful to the examination process.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

4. Claims 11, 16, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "said measuring equipment" in claim 1 or 2. There is insufficient antecedent basis for this limitation in claims 1 and 2.

Claim 16 recites the limitation "said reaction step" in claims 14 or 15. There is insufficient antecedent basis for this limitation in claims 14 and 15. Claim 17 is rejected for being dependent from the rejected claim 16 and also for failing to further clarify the basis of the rejection.

5. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation of the carrier being "an indeterminate member". It is noted that the specification does not provide a definition for an indeterminate member and therefore, by reading the claim, one of skill in the art would not understand what

Applicant is claiming. The metes and bounds of such a recitation cannot be determined and therefore, the claim is indefinite.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 9, and 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Safir et al. (U.S. Patent No. 6,491,823).

Safir et al. teach separation of polymers by using a carrier house/processing apparatus, wherein the apparatus comprises an injection valve, a chromatography column comprising a stationary phase, i.e., a carrier housing provided with an inlet/outlet, and an auto-sampler that withdraws the polymer from the sample container and delivers it to the chromatographic column, i.e., a drawing/discharging section (claims 1 and 14) (column 8, lines 54-67, column 26, lines 3-25, column 29, lines 8-11, column 34, lines 18-48 and 59-67, column 35, lines 1-27). Safir et al. teach that the auto sampler can be programmed to automatically sample different polymers one after another to serially load the polymers into the system, i.e., the apparatus of Safir et al. comprises a transferring section for the transfer of the inlet/outlet with respect to containers provided outside (claims 1 and 15), wherein the transferring section repeatedly draws and discharges a fluid with respect to the carrier housing (claim 16)

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(column 29, lines 50-67, column 30, lines 1-40). Safir et al. teach that the stationary phase comprises beads (i.e., particles), wherein the beads are made of silica (i.e., glass) or diverse polymers such as cross-linked resins and polystyrene (i.e., polymers that are able to be fixed or derivatized with a ligand) (claims 1, 4, 13, and 14) (column 41, lines 7-67, column 42, lines 1-30). Safir et al. also teach that a combination of carriers may be employed medium, such as a combination of carriers for size exclusion with carriers for adsorption chromatography, or reverse-phase chromatography carriers, i.e., Safir et al. teach a plurality of carriers that are a plurality of kinds (claim 5) (column 9, lines 7-15, column 37 bridging column 38). It is noted that the limitations of (i) the carrier not passing through the inlet/outlet (claims 1, 3, and 4), (ii) the carrier being held in the housing section by self- weight and carrier holding sections at the bottom (claims 1, 9, and 14), (iii) the carrier housing section having a large diameter enabling the carrier to pass through (claims 2, 3, and 17), (iv) the drawing/discharging section being provided with a detachable nozzle that connects with the opening that enables the carrier to pass through (claim 3), or (v) the inlet/outlet having a smaller diameter enabling insertion into containers provided outside (claim 2) are all inherent to any chromatographic column. Since Safir et al. teach all the claim limitations, the claimed invention is anticipated by the above-cited art.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-9, and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Safir et al., in view of both Tajima et al. (U.S. Patent No. 5,702,950) and Ikeda et al. (U.S. patent No. 6,607,662).

The teachings of Safir et al. are applied as above for claims 1-5, 9, and 13-17. Safir et al. do not teach a carrier comprising a magnetic substance, wherein the carrier is held in the housing section by a magnetic field applied from outside (claim 12). However, this is not innovative over the prior art, which teaches the use of magnetic particles in association with external magnetic fields in chromatographic separations, wherein the magnetic beads are held in the chromatographic column by the magnetic field (see for example Tajima et al., Abstract, column 3, lines 33-67; Ikeda et al., Abstract, column 8, lines 5-67, column 9, lines 1-19). It would have been obvious to one of skill in the art, at the time the invention was made to substitute the beads of Safir et al. with the combination of magnetic beads/magnetic field taught by the above cited art to achieve the predictable result of holding the carrier in the carrier housing (see *KSR International Co. v. Teleflex Inc.*, 550 U.S., 82 USPQ2d 1385, 2007). With respect to the diverse carriers recited in claims 4 and 8, it is noted that, although Safir et al. do not specifically disclose them, they do teach the use of diverse carriers such as beads, rods, monolithic carriers, or other shaped particles, wherein each carrier can be optimized fore a particular separation with respect to the material, size, shape, or pore size (column 35, lines 3-12). Therefore, one of skill in the art would have known to use

practically any type of carrier, including the claimed ones. With respect to the limitations recited in claims 6 and 7, these are not innovative over the prior art; one of skill in the art would have known to use the claimed adhesion prevention sections when needed. With respect to the limitation recited in claim 18, one of skill in the art would have known to remove the carrier when needed. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

10. Claims 1-5, 9, and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Safir et al., in view of Deschamps et al. (Protein Expression and Purification, 1995, 6: 555-568).

The teachings of Safir et al. are applied as above for claims 1-5, 9, and 13-17. Safir et al. do not teach a translucent carrier housing and an outside apparatus that measures luminescence on the carrier (claim 10). However, this is not innovative over the prior art. For example Deschamps et al. teach monitoring GFP chromatographic purification by using a translucent column and measuring GFP luminescence under black light (p. 556, columns 1 and 2). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the apparatus of Safir et al., by replacing their column with the column of Deschamps et al., with a reasonable expectation of success. One of skill in the art would have been motivated to do so in order to monitor the chromatographic purification of luminescent compounds, such as GFP. One of skill in the art would have been expected to have a reasonable expectation of success in making using such because the art teaches that such



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columns can be successfully used to follow GFP purification. The limitation of the carrier housing section having a side face made in a plane (claim 11) is again not innovative over the prior art. One of skill in the art would know to modify the carrier housing section according to the measuring equipment used. Thus, the claimed invention was *prima facie* obvious at the time the invention was made.

11. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ileana Popa whose telephone number is 571-272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ileana Popa, PhD

/Joseph Woitach/  
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SPE 1633